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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,035	10/31/2003	John Francis Bateman	071838.0142	3842

21003 7590 10/22/2008

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
10/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/699,035	BATEMAN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5,12,43 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12* is/are allowed.

6)☒ Claim(s) *4,43 and 44* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Attachments 1 &2*.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 8/1/08, is acknowledged.

2. Claims 4-5, 12 and 43-44 are pending and under examination in the instant application.

3. The New matter issue is herein withdrawn because the specification on pages 52-53, ¶142 discloses that the human homolog of WARP was identified by searching the genome data with the mouse WARP protein sequence. The human WARP gene is composed of four exons each of which encod a separate protein domain. First exon (73 bps in size) encodes the signal peptide, exon 2 (558 bps) encodes the VA-domain, exon 3 (279 bps) encodes the first F3 repeat and exon 4 (347) encodes the second F3 repeat. Accordingly, the total numbers of base pairs (bps) in the human gene is 73 + 558 +279 +347 = 1257 bps which is the same size of corrected SEQ ID NO: 5.

4. In view of the amendment filed on 8/1/08, only the following rejections are remained.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4 and 43-44 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for an isolated polypeptide, wherein the polypeptide is a von Willebrand Factor A-related Protein (WARP) encoded by the nucleotide sequence selected from the group consisting of: (i) "any" nucleotide sequence as set forth in SEQ ID NO: 5; and (ii) a nucleotide sequence capable of hybridizing to the complement of SEQ ID NO: 5 under high stringency conditions of 0.1 x SSC buffer, 0.1% w/v SDS at a temperature of at least 65°C, wherein said polypeptide specifically binds to an antibody directed toward a von Willebrand Factor type A domain in claim 4, or an isolated polypeptide, wherein said polypeptide comprises a von Willebrand Factor A-Related Protein (WARP) encoded by the nucleotide sequence selected from the group consisting of: (i) a nucleotide sequence having at least about 95% identity to SEQ ID NO: 5, and (ii) a nucleotide sequence having at least about 99% identity to SEQ ID NO: 5, wherein said polypeptide specifically binds to an antibody directed toward a von Willebrand Factor type A domain in claim 43, wherein the nucleotide sequence is at least 99% similar to SEQ ID NO: 5 in claim 44.

The skilled artisan would not reasonably expect a polypeptide having anything less than 100% identity *over the full length of SEQ ID NO:5* to *share the same function* as the polypeptide of SEQ ID NO:1. The limitation "said polypeptide specifically binds to an antibody directed toward a von Willebrand Factor type A domain" is not seen as providing a requisite functional activity for the nucleic acid encoding the polypeptide both because an antibody epitope may be as small as 6-15 shared amino acid residues and places no limitations on the function of the protein containing the polypeptide sequence recognized. Thus the recitation of percent identity language, in the absence of *a testable function* and limitations regarding the *sequence length over which the percent identity is required*; does not allow the skilled artisan to make and use the encoding nucleic acids commensurate in scope with the instant claims without undue experimentation.

The term "a nucleotide sequence asset forth in SEQ ID NO: 5" reads on the full-length sequence of SEQ ID NO: 5 or any portion of SEQ ID NO: 5. Claim 4 would encompass any sequence of two or more nucleotides fully contained within SEQ ID NO: 5. The recitation "the" nucleotide sequence asset forth in SEQ ID NO: 5 would obviate this issue.

Applicant's arguments, filed 8/1/08, have been fully considered, but have not been found convincing.

Applicant submits that the present application links structure to function by describing important structural domains in the WARP protein sequence, as such, one skilled in the art would be able to use identify a functional WARP protein by looking for these domains, as discussed above. The Examiner concedes on page 4, bottom paragraph, of the present office action that "in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein." The present claims are therefore enabled because Applicants have defined important conserved domains of the WARP protein which one skilled in the art may depend on to assess the function of the isolated polypeptide claimed in the present invention. Applicants have also amended the claims to link the structure of the claimed polypeptide to its function. Based on the preceding argument.

However, antibody binding to a polypeptide is not seen as providing a requisite functional activity since an antibody epitope may be as small as 6-15 shared amino acid residues and places no limitations on the function of the protein containing the polypeptide sequence recognized.

7. The following new ground of rejections are necessitated by the amendment submitted 8/1/08.

8. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The recitation "99% similar" in claim 44 lacks sufficient antecedent bases in base claim 43. Base claim 44 only recites "99% identity".

9. Claims 4 and 43-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons*:

The phrase "wherein said polypeptide specifically binds to an antibody directed toward a von Willebrand Factor type A domain" claimed in claims 4 and 43 represents a departure from the specification and the claims as originally filed.

Applicant's amendment filed 8/1/08 points to the specification at example 5, original claim 34 and ¶¶ 88, 90 and 91 for support for the newly added limitation. However, the specification and the claims do not provide a clear support for the new limitation. The specification and the claims as originally filed only contemplate an antibody to specific sequences. However, the instant claimed antibodies would recognize a genus of polypeptides which encoded by a nucleotide sequence capable of hybridizing to the complement of SEQ ID NO: 5. A subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads, see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 4 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by US. Pat. 7,368,531.

The `531 patent teaches a polypeptide sequence encoded by 734 bps nucleic acid sequence (see published SEQ ID NO: 2635) which has 99.7% similarity to claimed SEQ ID NO:5. The referenced SEQ ID NO:2635 would hybridize to the complement of SEQ ID NO: 5 under stringent conditions (see attached sequence alignment). An antibody against von Willebrand Factor Type A would bind to the referenced polypeptide in the absence of evidence to the contrary.

The reference teachings anticipate the claimed invention.

12. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by US. Pat. 7,129,338.

The `338 patent teaches a 550 polynucleotide sequence that would encode a polypeptide. The referenced polynucleotide is 97% similar to SEQ ID NO: 5 and would hybridize to the complement of claimed SEQ ID NO: 5 under stringent conditions (see attached sequence alignment).). An antibody against von Willebrand Factor Type A would bind to the referenced polypeptide in the absence of evidence to the contrary.

The reference teachings anticipate the claimed invention

13. Claim 12 is allowable.

14. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 9, 2008

/Maher M. Haddad/
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